K072082

BioMeDevice Ltd.
24931 Nellie Gail Rd.
Laguna Hills, CA 92653
Tel. 949-362-9407
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NOV - 5 2007

510K SUMMARY

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510K number is:

1. Submitter's Identification:

   BioMeDevice Ltd.
   24931 Nielie Gail
   Laguna Hills, California 92653
   Telephone: 949-362-9407
   Facsimile: 949-362-

   Contact Person: Brice Yoder, Office of the Chairman

   Date of Summary: 7-27-07

2. Device Name: gumEase® dental mouthpiece

3. Classification Name: Not Classified

4. Predicate Device:

   a. K963666 – Instant Cold Pack by Kick Ice, Inc.
   b. K970399 - Kwik Kold™ Peri Cold Pack by Allegiance Healthcare Corporation.
   c. K002066 – Freezer Teether by Cool Baby Inc.

5. Intended Use: The gumEase® dental mouth piece provides temporary relief from oral discomfort resulting from dental work, brace pain, denture irritation, post surgical pain, or minor oral trauma.

6. Device Description/ Comparison: The gumEase® dental mouth piece is manufactured from biocompatible plastic tubing that is filled with a NaCl solution. Substantial equivalent to the predicate devices was established by principle of operation, device design and similarity of indication of use. Biocompatibility testing was performed in accordance with the ISO 1993 guidelines and all test results demonstrated that the gumEase® dental mouth piece is biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2007

Dr. Brice L. Yoder
Chief Executive Officer
BioMeDevice, Limited
24931 Nellie Gail Road
Laguna Hills, California 92653

Re: K072082
Trade/Device Name: GumEase® Dental Mouth Piece
Regulation Number: 872.5550
Regulation Name: Teething Ring
Regulatory Class: II
Product Code: KKO
Dated: October 25, 2007
Received: October 26, 2007

Dear Dr. Yoder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

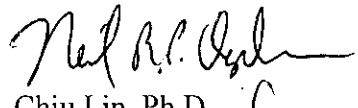
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072082

Device Name: gumEase® dental mouth piece

Indications For Use:

The gumEase® dental mouthpiece provides temporary relief from oral discomfort resulting from dental work, brace pain, denture irritation, post surgical pain or minor oral trauma.

Prescription Use ✓ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number: K072082